

SUPPLEMENTAL NOTICE OF ALLOWABILITY

SUPPLEMENTAL EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Armstrong on 4/29/2010.

Amend the claims by replacing claim 1 with the following:

Claim 1. (Amended) A transgenic mouse or rat whose genome comprises a foreign DNA, the foreign DNA comprising a type II collagen promoter and a type II collagen enhancer operably linked to a polynucleotide that encodes a MHC class II transactivator gene, wherein administration of type II collagen to said transgenic mouse or rat at a dose of 0.01 mg to 0.05 mg two or more times results in presentation of pathologic conditions of human rheumatoid arthritis in said transgenic mouse or rat, wherein the transgenic mouse or rat shows the following pathologic conditions (1) to (6):

- (1) Joint swelling is observed in the whole body;
- (2) Joint swelling lasting for a week or more is observed;
- (3) Destruction, ankylosis, or deformity of bones in the extremities is observed;
- (4) Infiltration of lymphoid cells is observed;
- (5) Cartilage destruction and bone destruction due to formation of granulation tissue are observed; and
- (6) Joint deformity progresses through early stage (stage I) and moderate stage (stage II).

SUPPLEMENTAL REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The prosecution history provides evidence for allowability.

In addition, post-filing publication (Kanazawa et al. (PNAS. 26 Spet 2006; 103(39): 14465-14470), indicates differences between the claimed model and the collagen induced arthritis (CIA) model. Kanazawa et al. indicate that conventional low-dose CIA animal models required 20-40 times more collagen than the Applicant's Col2pro/enh-CIIITA transgenic model elicit RA symptoms (page 14466, col.1, lines 509). Kanazawa states that the amount of collagen administered to the claimed mouse which was sufficient to elicit RA symptoms was insufficient to elicit RA symptoms in the conventional CIA models (page 14467, Discussion). Kanazawa et al further indicate that the duration of inflammation in their mice was twice as long as in the conventional CIA model (page 14466, col.1, lines 15-16). Kanazawa et al. also teach that the applicant's claimed model demonstrates ankylosis, while the CIA model does not (page 14467, col.1, last few lines bridging column 2). These considerations, together with the fact that the claimed transgenic rat/mouse had never been made, provides further evidence of the novelty of the claimed rat/mouse. The instantly claimed invention is a distinctly new animal model that was not previously available to researchers.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

EXAMINER CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Long whose telephone number is 571-272-9048.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SCOTT LONG/

Primary Examiner, Art Unit 1633